DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

March 13, 2017

Thermi
Ms. Suzanne Cheang
Regulatory Affairs Manager
8304 Esters Boulevard
Irving, Texas 75063

Re: K170116
Trade/Device Name: Thermi Injectable RF Electrodes
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and acessories
Regulatory Class: Class II
Product Code: GEI
Dated: December 21, 2016
Received: January 13, 2017

Dear Ms. Cheang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Jennifer R. Stevenson -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K170116

Device Name

Thermi Injectable RF® Electrodes

Indications for Use *(Describe)*

The Thermi Injectable RF® Electrodes used with the Thermi RF Generator System are indicated:
*for use in dermatological and general surgical procedures for electrocoagulation and hemostasis
* to create lesions in nervous tissue when used in combination with Thermi RF Generator.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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SECTION 5: 510(k) SUMMARY

This 510(k) Summary is submitted in accordance with the requirements of 21 CFR 8.7.87 and 807.92.

I. SUBMITTER

Date Prepared	March 09, 2017
Company	Thermi 8304 Esters Boulevard Ste 890 Irving, TX 75063
Contact	Ms. Suzanne Cheang, BS Regulatory Affairs Manager Telephone: 214-888-0683 Fax: 214-279-0101 scheang@thermi.com

II. DEVICE

Trade Name	Thermi Injectable RF® Electrodes
Common Name	Electrosurgical Cutting and Coagulation Device and Accessories
Classification Name	21 CFR 878.4400 Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class	II
Product Code	GEI

III. PREDICATE DEVICE

Predicate Name	Thermi RF Accessories, K161661

IV. DEVICE DESCRIPTION

The Thermi Injectable RF® Electrodes are designed to provide finely-controlled radiofrequency (RF) energy in combination with the Thermi RF Generator. They are not intended to function with other RF generators or other non-Thermi branded products.

The Injectable RF® Electrodes are a combination of a RF electrode and a RF cannula to allow percutaneous application of RF energy. The RF electrode delivers the RF signal from the generator to the active tip of the cannula. The device utilizes an insulated shaft along the outside of the cannula to avoid transition of the RF signal outside of the tip area. From the active tip, the RF signal causes the tissue molecules to vibrate resulting in the formation of heat. The heated area is a function of the active tip size (length, gauge). The device is offered in different sizes to accommodate multiple anatomies and desired heating areas. The device connects to a Thermi RF Generator and requires the use of a grounding pad to complete the circuit.

The Injectable RF® Electrodes are available in different lengths, different tip exposures and different thicknesses. The lengths that are available for the Thermi Injectable RF® Electrodes range from 5 cm to 20 cm. The cannula portion is coated with an insulation layer such that only the tip will transmit the RF signal and ablate the tissue. The tip exposures available for the Thermi Injectable RF® Electrodes range from 5 mm to 10 mm. The diameters available for the Thermi Injectable RF® Electrodes range from 16 GA to 20 GA. The cannula electrodes have a blunt tip. All the RF electrodes have a 264 cm long silicone cable. The disposable cannula electrode is provided sterile in a sealed tray for single use only.

V. INDICATIONS FOR USE

The Thermi Injectable RF® Electrodes used with the Thermi RF Generator System are indicated:

* for use in dermatological and general surgical procedures for electrocoagulation and hemostasis
* to create lesions in nervous tissue when used in combination with Thermi RF Generator.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The Thermi Injectable RF® Electrodes are substantially equivalent to the Thermi RF Accessories, cleared under 510(k) K161661, in terms of design, functional performance, and intended use. The Thermi Injectable RF® Electrodes combine the separate electrodes and cannulas described in the Thermi RF Accessories 510(k) K161661 into single devices, which reduces procedure steps and time. There is no change to the fundamental scientific technology of the previously cleared devices or their indications for use as compared to the Thermi RF Accessories.

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Electrical safety

Electrical safety testing was conducted on the Thermi Injectable RF® Electrodes and ThermiRF Generator. Compliance was demonstrated through testing to IEC 60601-1: 2006, IEC 60601-1-2: 2001, IEC 60601-1-4: 1996, IEC 60601-1-6: 2006 and IEC 60601-2-2: 2009.

Bench testing

A series of bench testing was conducted on the Thermi Injectable RF® Electrodes in accordance with protocols to verify design specifications as follows: dimensional testing, functional testing, design features, tensile strength, packaging, shipping and shelf-life.

The functional and simulated use verification testing was completed to demonstrate that the Thermi Injectable RF® Electrodes will function as intended when used with the Thermi RF Generator.

The results of testing show that the Thermi Injectable RF® Electrodes, met all performance and functional testing and performed as intended; and did not raise new safety or performance questions.

VIII. CONCLUSIONS

The results of testing show that the Thermi Injectable RF® Electrodes, met all performance and functional testing and performed as intended; and did not raise new safety or performance questions when use with Thermi RF Generator. The means of achieving electrocoagulation and hemostasis and creating lesions in nervous tissue in dermatological and general surgical procedures with the Thermi Injectable RF® Electrodes is substantially equivalent to the predicate devices.